

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Perricaudet et al. Group Art Unit: .
International Application No: PCT/FR96/00218
Serial No.: 08/894,246 Examiner:
Filing Date: 14 August 1997

For: Medicinal Combination Useful For In Vivo Exogenic Transfection and Expression

To: The Honorable Commissioner of Patents and Trademarks
Washington, D.C. 20231

CERTIFICATE OF MAILING (37 CFR § 1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Date: September 9, 1997

Paula L. Dickey
(Type or print name of person mailing paper)

Paula L. Dickey
(Signature of person mailing paper)

INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §§ 1.97 AND 1.98

Dear Sir:

Applicants submit herewith a list of patents and publications which Applicants believe the Examiner may consider to be material to the patentability of claims of this application and which there may be a duty to disclose in accordance with 37 CFR § 1.56.

These patents and publications were cited in the International Search Report, and have been sent to the USPTO as an Elected Office.

Patent FC is in the French language. As a concise explanation of the relevance of Patent FC as it is presently understood, Applicants submit herewith: (1) an English translation of the International Search Report (Appendix 1), showing the relevance found by the International Search

BEST AVAILABLE COPY

Authority; and (2) an English language translation of Section V of the International Preliminary Examination Report (Appendix 2), showing the relevance found by the International Preliminary Examination Authority.

While the patents and publications disclosed herein may be "material" within the meaning of 37 CFR § 1.56, Applicants' inclusion thereof in this Statement is not intended to constitute an admission that any such patent or publication is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR § 1.97 (g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that the information cited is material to patentability as defined in 37 CFR § 1.56(b).

Applicants believe that the claims in the present application are patentably distinguishable over the patents and publications listed on the attached Information Disclosure Citation Form.

This Information Disclosure Statement is being filed before the first Office Action on the merits of this application and accordingly, pursuant to 37 CFR § 1.97 (b)(3), this statement requires neither a fee nor a certification.

Rhône-Poulenc Rorer Inc.
P.O. Box 5093, Mail Stop 3C43
Collegeville, PA 19426-0997
Telephone: (610) 454-3839
Facsimile: (610) 454-3808

Dated: 9/2/97

Respectfully submitted,



Paul F. Fehlner, Ph.D.
Attorney for Applicants
Registration No: 35,135

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

later: final Application No
PCT/FR 96/00218

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61K48/00 //C12N15/86

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO.A.94 16080 (EXEMPLAR CORPORATION) 21 July 1994 see examples see claims	1-25
Y	--- BRITISH MEDICAL BULLETIN, vol. 51, no. 1, EDINBURGH, GB, pages 31-44, XP002003907 E. KREMER ET AL.: "Adenovirus and adeno-associated virus mediated gene transfer." see abstract see page 41, line 24 - line 36	1-25
Y	--- WO.A.94 28152 (TRANSGENE S.A.) 8 December 1994 see examples see claims	1-25
	--- -/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

A document member of the same patent family

Date of the actual completion of the international search

24 May 1996

Date of mailing of the international search report

07. 06.96

Name and mailing address of the ISA

European Patent Office, P.B. 5118 Palatzen 2
NL - 2200 HV Rijswijk
Tel. (+31-70) 340-2040, Telex 31 631 epo nl,
Fax (+31-70) 340-3016

Authorized officer

Nooij, F

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

International Application No.

PC1/FR 96/00218

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of documents, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO,A,94 16065 (EXEMPLAR CORPORATION) 21 July 1994 see examples see claims ---	1-25
P,O, X	JOURNAL OF CELLULAR BIOCHEMISTRY, SUPPLEMENT, vol. 8, no. 21A, 31 March 1995, NEW YORK, NY, USA, page 359 XP002003908 M. LEE ET AL.: "Reducing the immune response against adenoviral vectors." voir abrégé C6-017 ---	1-25
P,A	GENE THERAPY, vol. 2, no. 4, June 1995, BASINGSTOKE, GB, pages 256-262, XP000571413 M. LEE ET AL.: "The constitutive expression of the immunomodulatory gp19K protein in E1-, E3-adenoviral vectors strongly reduces the host cytotoxic T cell response against the vector." see the whole document -----	1-25

BEST AVAILABLE COPY

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR96/00218

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

Claim 1 does not appear to be supported by the description: cf. point 3) in "Citations and Explanations".

BEST AVAILABLE COPY

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR96/00218

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. STATEMENT

Novelty	Claims	1-25_____	YES
	Claims	_____	NO
Inventive Step	Claims	1-25_____	YES
	Claims	_____	NO
Industrial Applicability	Claims	1-25_____	YES
	Claims	_____	NO

2. CITATIONS AND EXPLANATIONS

1. Given that it is not possible to compare the "reporter" gene of WO-A-94/16080 (1) with the "therapeutic" gene of the present application, claims 1 to 25 are novel.
2. In view of the tests demonstrating the synergy between the immunosuppressive agent and the recombinant adenovirus, which is the subject of claims 1 to 25, these claims are inventive.
3. Lines 21 and 22 on page 12 of the description indicate that the adenovirus which is used in the claimed medicinal combination is defective, a fact which it would seem to be necessary to make clear in claim 1.
4. There is also a lack of clarity in the following claims:
 - Claim 11 should refer to claims 1 to 9, since it is in contradiction with Claim 10.
 - For the same reasons, claims 23 and 25 should refer back to claims 21 (and not 22) and 1 to 23, respectively.

BEST AVAILABLE COPY

U.S. Department of Commerce
Patent and Trademark Office

(use as many sheets as necessary)

Application Number	08/894,246
Filing Date	14 August 1997
First Named Inventor	Perricaudet et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	EX95001-US

Sheet	1	of	2
-------	---	----	---

[illegible][illegible]

DATE CONSIDERED

Turnaround Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, D.C. 20231.

Please type a plus sign (+) inside this box ☐449A/PTO U.S. Department of Commerce
Patent and Trademark Office**LIST OF PRIOR ART CITED BY
APPLICANT**

(use as many sheets as necessary)

Complete if Known

Application Number	08/894,246
Filing Date	
First Named Inventor	14 August 1997
Group Art Unit	Perricaudet et al.
Examiner Name	
Attorney Docket Number	EX95001 - US

Sheet	2	of	2
-------	---	----	---

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.	T ²
	PA	Lee et al., Reducing The Immune Response Against Adenoviral Vectors, Journal of Cellular Biochemistry Supp. 0(21A), 359 (1995)	
	PB	Lee et al., The constitutive expression of the immunomodulatory gp 91k protein in E1-, E3- adenoviral vectors strongly reduces the host cytotoxic T cell response against the vector, Gene Therapy, 2, 256-262 (1995)	
	PC	Kremer et al., Adenovirus and adeno-associated virus mediated gene transfer, British Medical Bulletin, 51(1), 31-44 (1995)	

EXAMINER SIGNATURE

DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

Order Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, D.C. 20231.

BEST AVAILABLE COPY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of: Perricaudet et al. Group Art Unit: 1633
Serial No. 08/894,246 Examiner: S. Chen
International Filing Date: February 12, 1996

For: Medicinal Combination Useful For In Vivo Exogenic Transfection And
Expression

To: Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the: Assistant Commissioner for Patents, Washington, D.C. 20231.

Paula L. Dickey
(Type or print name of person mailing paper)

Date: December 8, 1999

Paula L. Dickey
(Signature of person mailing paper)

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
PURSUANT TO 37 CFR §§ 1.97 AND 1.98

Dear Sir:

Applicant submits herewith a list of patents and publications PD and PE, and copies thereof, as required by 37 C.F.R. § 1.98, which Applicant believes the Examiner may consider to be material to the patentability of claims of this application and for which there may be a duty to disclose in accordance with 37 CFR § 1.56. Applicant has previously filed an Information Disclosure Statement for this application on September 9, 1997.

While the patents and publications disclosed herein may be "material" within the meaning of 37 CFR § 1.56, Applicant's inclusion thereof in this Information Disclosure Statement is not intended to constitute an admission that any such patent or publication is "prior art" for this invention unless specifically designated as such.

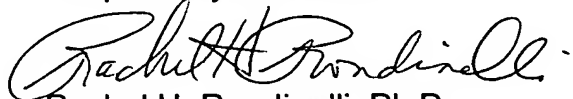
BEST AVAILABLE COPY

In accordance with 37 CFR § 1.97 (g) and (h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that the information cited is material to patentability as defined in 37 CFR § 1.56(b).

Applicant believes that the claims in the present application are patentably distinguishable over the patents and publications listed on the attached Information Disclosure Citation Form.

This Information Disclosure Statement is being filed after the mailing date of the first Office Action on the merits but before the mailing date of a final action under 37 C.F.R. § 1.113 or a notice of allowance under 37 C.F.R. § 1.311. The Commissioner is hereby authorized to deduct the fee of \$240.00 for submission of this Information Disclosure Statement, pursuant to 37 C.F.R. §§ 1.97 (c) and 1.17 (p), from Deposit Account No. 18-1982. The Commissioner is hereby authorized also to deduct any underpayment from, or credit any overpayment further to the filing of this Information Disclosure Statement to said Deposit Account. An original and one copy of this Statement are enclosed.

Respectfully submitted,



Rachel H. Rondinelli, Ph.D.
Agent for Applicant
Registration No: 45,052

Dated: December 7, 1999

Rhône-Poulenc Rorer Inc.
Mailstop #3C43
P.O. Box 5093
Collegeville, PA 19426-0997
Telephone: (610) 454-3178
Facsimile: (610) 454-3808

BEST AVAILABLE COPY

Please type a plus sign (+) inside this box



1449A/PTO		U.S. Department of Commerce Patent and Trademark Office		Complete if Known	
LIST OF PRIOR ART CITED BY APPLICANT (use as many sheets as necessary)				Application Number	08/894,246
				Filing Date	Feb. 12, 1996 (Intl.)
				First Named Inventor	Perricaudet et al.
				Group Art Unit	1633
				Examiner Name	S. Chen
Sheet	1	of	1	Attorney Docket Number	EX95001 -US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, country, where published, source.
	PD	Kay et al., Long-term hepatic adenovirus-mediated gene expression in mice following CTLA4lg administration, Nature Genetics 11, 191-197 (1995)
	PE	Kay et al., Transient immunomodulation with anti-CD40 ligand antibody and CTLA4Ig enhances persistence and secondary adenovirus-mediated gene transfer into mouse liver, Proc. Natl. Acad. Sci. USA 94, 4686-4691 (1997)

BEST AVAILABLE COPY

EXAMINER SIGNATURE	DATE CONSIDERED
--------------------	-----------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Unique citation designation number. Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer,

+

PTO/SB/08A (6-95)

APTO

U.S. Department of Commerce
Patent and Trademark Office

LIST OF PRIOR ART CITED BY

(use as many sheets as necessary)

Complete if Known

Application Number	08/894,246
Filing Date	14 August 1997
First Named Inventor	Pe and others et al.
Group Art Unit	
Examiner Name	
Attorney Docket Number	EX95001-US

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

EXAMINER'S SIGNATURE

Shih-Lin Chen

~~DATE CONSIDERED~~

6-1-99

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609/Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.1 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take .2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, D.C. 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, D.C. 20231.

Notice of References Cited

Application/Control No.

08/894,246

Examiner

Shin-Lin Chen

Applicant(s)/Patent Under
Reexamination
PERRICAUDET ET AL.

Art Unit

1633

Page 1 of 1

U.S. PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	NAME	CLASS	SUBCLASS	DOCUMENT SOURCE **	
							APS	OTHER
<input type="checkbox"/>	A						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	B						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	C						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	D						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	E						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	F						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	G						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	H						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	I						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	J						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	K						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	L						<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	M						<input type="checkbox"/>	<input type="checkbox"/>

FOREIGN PATENT DOCUMENTS

*		DOCUMENT NO.	DATE	COUNTRY	NAME	CLASS	SUBCLASS	DOCUMENT SOURCE **	
								APS	OTHER
<input type="checkbox"/>	N							<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	O							<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	P							<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	Q							<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	R							<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	S							<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	T							<input type="checkbox"/>	<input type="checkbox"/>

NON-PATENT DOCUMENTS

*		DOCUMENT (Including Author, Title Date, Source, and Pertinent Pages)	DOCUMENT SOURCE **	
			APS	OTHER
<input type="checkbox"/>	U	Verma et al., Gene therapy-promises, problemes and prospects, September 1997, Nature Vol. 389, pages 239-242	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	V	Eck et al., Gene-Based Therapy, Goodman & Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition, Chapter 5, pages 77-101	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	W		<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/>	X		<input type="checkbox"/>	<input type="checkbox"/>

*A copy of this reference is not being furnished with this Office action. (See Manual of Patent Examining Procedure, Section 707.05(a).)

**APS encompasses any electronic search i.e. text, image, and Commercial Databases.

U.S. Patent and Trademark Office

PTO-892 (Rev. 03-98)

Notice of References Cited

Part of Paper No. 16

BEST AVAILABLE COPY

Notice of References Cited

Application/Control No.

08/894,246

Applicant(s)/Patent Under
Reexamination
PERRICAUDET ET AL.

Examiner

Shin-Lin Chen

Art Unit

1633

Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-			
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

BEST AVAILABLE COPY

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Nabel et.al.; Recombinant Growth Factor Gene Expression in Vascular Cells in Vivo, 1994, Annals New York Academy of Sciences, Vol. 714: 247-252.
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.